

Soy protein supplementation does not reduce risk of prostate cancer recurrence

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Among men who had undergone radical prostatectomy, daily consumption of a beverage powder supplement containing soy protein isolate for 2 years did not reduce or delay development of biochemical recurrence of prostate cancer compared to men who received placebo, according to a study in the July 10 issue of *JAMA*.

"Prostate cancer is the most frequently diagnosed [malignancy](#) and the second most frequent cause of male [cancer death](#) in the United States and other Western countries but is far less frequent in Asian countries. Prostate cancer risk has been inversely associated with intake of soy and soy foods in [observational studies](#), which may explain this [geographic variation](#) because soy consumption is low in the United States and high in Asian countries," according to background information in the article.

"Although it has been repeatedly proposed that soy may prevent prostate [cancer development](#), this hypothesis has not been tested in randomized studies with cancer as the end point. A substantive fraction (48 percent - 55 percent) of men diagnosed as having [prostate cancer](#) use [dietary supplements](#) including soy products, although the exact proportion is not known. However, no evidence exists that soy supplementation has any prostate cancer-related benefits for these men. Soy contains several constituents, including isoflavones, which possess anticancer activities in laboratory studies."

Maarten C. Bosland, D.V.Sc., Ph.D., of the University of Illinois at Chicago, and colleagues examined whether daily consumption of a [soy](#)

[protein](#)-based supplement would reduce the rate of recurrence or delayed recurrence of prostate cancer in men at high risk of recurrence after radical [prostatectomy](#). The [randomized trial](#) was conducted from July 1997 to May 2010 at 7 U.S. centers and included 177 men. Supplement intervention was started within 4 months after surgery and continued daily for up to 2 years, with prostate-specific antigen (PSA) measurements made at 2-month intervals in the first year and every 3 months thereafter. Participants were randomized to receive a daily serving of a beverage powder containing 20 g of protein in the form of either soy protein isolate (n=87) or as placebo, calcium caseinate (n=90).

The trial was stopped early for lack of treatment effects at a planned interim analysis with 81 evaluable participants in the intervention group and 78 in the placebo group. Overall, 28.3 percent of participants developed biochemical recurrence (defined as development of a PSA level of ≥ 0.07 ng/mL) within 2 years of entering the trial. Twenty two (27.2 percent) of the participants in the intervention group developed confirmed biochemical recurrence, whereas 23 (29.5 percent) of the participants receiving placebo developed recurrence. "Among participants who developed recurrence, the median [midpoint] time to recurrence was somewhat shorter in the intervention group (31.5 weeks) than in the placebo group (44 weeks), but this difference was not statistically significant," the authors write.

Adherence was greater than 90 percent. There were no differences in adverse events between the 2 groups.

"The findings of this study provide another example that associations in observational epidemiologic studies between purported preventive agents and clinical outcomes need confirmation in randomized clinical trials. Not only were these findings at variance with the epidemiologic evidence on soy consumption and [prostate cancer risk](#), they were also not consistent with results from experiments with animal models of prostate

carcinogenesis, which also suggest reduced risk," the researchers write.

"One possible explanation for these discrepant results is that in both epidemiologic studies and animal experiments, soy exposure typically occurred for most or all of the life span of the study participants or animals; there are no reports of such studies in which soy exposure started later in life. Thus, it is conceivable that soy is protective against prostate cancer when consumption begins early in life but not later or when prostate cancer is already present. If this is the case, chemoprevention of prostate cancer with soy is unlikely to be effective if started later in life, given the high prevalence of undetected prostate cancer in middle-aged men."

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